REMARKS

Favorable reconsideration of the pending claims is respectfully requested in view of the above amendments and following remarks. Claims 2-5, 10, 17, 19, 20 and 22-28 are pending in the application, with claims 19 and 20 being in independent format.

The rejection of claims stated in the final Office action mailed June 7, 2011 was appealed, with a request for review pursuant to the Pre-Appeal Brief Conference Pilot Program. Prosecution was re-opened as a consequence of the Pre-Appeal Brief Review, and a new non-final action was mailed Feb. 22, 2012. This submittal is in response to the non-final action and is being submitted within the shortened statutory period set for response. No extension of time fee is therefore required.

Claims 19 and 20 are amended for purposes of clarification. Claim 19 is amended to recite the catheter element prior to the recitation of the rotatable torque tube and liner in an effort to clarify the structural relationships among the claim elements. The catheter has a proximal end terminating within the housing at an aspiration site and a distal end terminating at an operating head, and the catheter forms an aspiration lumen extending from the aspiration site to the operating head. This aspect of applicants' claimed aspirating catheter device is described, for example, in the specification as filed and as published at Paragraphs 0049 and 0050. Claim 19 has also been amended to clarify that the liner terminates distally at an intersect area located proximal to the distal end of the torque tube and within the aspiration lumen, and to specify that liquid infused into the flood space during operation of the aspiration catheter device forms a seal around the proximal end of the torque tube and exits the flood space at the intersect area within the aspiration lumen. These aspects of applicants' claimed aspirating catheter device are described, for example, in the specification as filed and as published at Paragraphs 0014 and 0044 and shown in Fig. 3. Claim 20 is similarly amended. Applicants submit that these amendments are supported by the specification as it was originally filed and do not give rise to prosecution history estoppel.

Claim rejections under 35 USC §103

Claims 2-5, 10, 17, 19, 20, 22-24 and 26-28 stand rejected under 35 USC §103(a) as being unpatentable over U.S. Patent no. 5,217,474 to Zacca et al. in view of U.S. Patent No. 6,080,170 to Nash et al. Claim 25 stands rejected 35 USC §103(a) as being obvious over Zacca et al in view of Nash et al. and further in view of US Patent No. 6,258,052 to Milo. This rejection is respectfully traversed in view of the clarifying amendments presented above and the explanatory remarks provided below. Applicants in this response rely on the amendments and arguments presented in

connection with independent claims 19 and 20, which are believed to place the independent claims (and consequently all of the claims) in condition for allowance.

The outstanding rejection relies on the same references as the final rejection, which was appealed, but changes the order of the primary and secondary references. Prosecution of this application has been extensive. ***Applicants request a phone interview with the Examiner following her review of this Amendment and Reply to discuss applicants' pending claims and their patentability in view of the prior art relied upon for rejection and this response.***

Applicants' aspirating catheter device incorporates a liquid sealing assembly and liquid seal site to prevent air and other fluids from seeping into the system at the location where the rotating drive shaft enters an area of high vacuum, typically at the proximal end of an aspiration lumen. Rotating drive shafts in aspirating catheter devices are typically sealed to prevent air leakage into the system using mechanical sealing mechanisms such as O-rings, bushings and bearings. As the drive shaft rotates at high speed during operation of the medical device, the mechanical seals break down and are prone to leakage as a result of frictional heating and degradation.

In applicants' claimed devices, a liner is provided surrounding the rotatable torque tube at a sealing site within a housing, and the liner forms a flood space between the inner liner surface and the torque. Liquid is infused into the flood space formed between the liner and the torque tube at the sealing site during high speed rotation of the torque tube, and the liquid forms a cushion around the torque tube, providing a seal that prevents air and other fluids from entering the system at the sealing site. Liquid infused into the flood space at the sealing site flows distally, within the flood space, and exits the liner at an intersect area proximal of the distal end of the catheter *and within an aspiration lumen* (*See, e.g.*, Fig. 3). In this way, the sealing liquid enters the aspiration lumen and is simply withdrawn with aspirate as the system operates.

Both Zacca et al. and Nash et al. teach interventional catheter devices that have infusion systems that the Examiner likens to applicants' claimed "liner" and "liquid flood space." The sealing features and structures of Applicants' claimed aspirating catheter device, which use liquid in a liner surrounding the drive train to provide a seal and prevent air leakage into the system, is *not* an infusion system that delivers infusion liquids to the area of a working head.

Zacca et al. discloses an atherectomy assembly that infuses (*e.g.*, injects a contrast medium or cooling fluid) through an annular space (34) formed between the outer surface of the drive shaft and the inner surface of an outer catheter (14). As shown in Figs. 2 and 3, catheter (14), and

therefore annular space 34, terminates at a distal region proximal of the working head. The Examiner refers to catheter (14) of Zacca et al. as a "liner" and the terminal location of catheter (14) as an "intersect area." Zacca et al. specifically refer to catheter (14) as an *outer* catheter (*See, e.g.,* Col. 6, lines 39-44, Figs. 1-3 and 5), while in applicants' claimed device, *the liner is explicitly positioned within the catheter*. The outer catheter of Zacca et al. cannot be referred or considered equivalent to the "liner" as recited in applicants' claims; the outer catheter of Zacca et al. is neither structurally nor functionally equivalent to the liner specified in applicants' claims. Furthermore, the catheter (14) of Zacca et al. does not terminate at an "intersect area" as recited in applicants' pending independent claims. Applicants' claims specify that the liner extends from a sealing site (within the housing) longitudinally less than the axial length of the torque tube and terminates distally at an intersect area located proximal to the distal end of the torque tube *and within the aspiration lumen*. Zacca's atherectomy assembly does not have an aspiration lumen and its outer catheter (14) thus cannot create an "intersect area" as claimed, positioned within an aspiration lumen. Zacca et al. thus fail to disclose or suggest either a "liner" element or an "intersect area" as specified in applicants' pending claims.

The Examiner acknowledges that Zacca et al. fail to disclose an "aspiration catheter" that encloses the torque tube and liner and provides an aspiration lumen and relies on Nash et al. for disclosure of an aspiration catheter. Nash et al. disclose an atherectomy catheter in which a distal working head impacts occlusive material to open a lumen and infusate liquid is introduced through a catheter jacket (34) adjacent the working head. Infusate exits the interior of catheter jacket (34) through ports in a shroud positioned at the working head (*See*, Col. 8, lines 48-59 and Figs. 3, 4.) The infusate delivered to the site of the working head, as well as blood and debris generated during operation of the Nash device, are withdrawn by aspiration through a guide catheter positioned proximally of the infusion location. Positioning the guide catheter forming the aspiration lumen a distance proximally of the working head and infusate exit is required to provide the desired flow characteristics for debris, blood and infusate. (*See, e.g.,* Fig. 10). The fluid flow system of Nash et al. is carefully managed by adjustment of infusate and aspiration flow rates and by positioning the aspiration entry at a distance proximally of the infusion exit to create a differential flow adjacent the working head, to assist the withdrawal of debris generated by operation of the working head. (*See*, Col. 5, lines 6-15.) Although the Examiner posits moving the guide catheter of Nash et al. (as applied to Zacca et al.) to a position where its distal end extends beyond the distal end of the infusate

exit location, the teachings of Nash et al. are in direct conflict with this proposal. Moving the guide catheter of Nash et al. would defeat the purpose and destroy the function of the Nash et al. system. Applicants submit there is no reasonable rationale for modifying either Nash et al. or Zacca et al. in this fashion.

Applicants do not perceive any combination of the features of Nash et al. with those of Zacca et al. that would result in applicants' claimed aspirating catheter device. Furthermore, applicants submit that one of ordinary skill in the art would *not* combine the aspiration features of Nash et al. with the atherectomy device taught by Zacca et al. as proposed by the Examiner. The Examiner states that it would have been obvious to one of ordinary skill in the art to enclose the atherectomy device of Zacca with an aspiration catheter, as taught by Nash, in order to provide a means for removing debris from the treatment site and preventing it from flowing into other areas of the bloodstream. (*See*, outstanding action, paragraph spanning pages 4, 5.) Zacca et al. teach that the particles of stenotic material abraded by the device are smaller than red blood cells and can therefore be disposed of naturally by the body. Zacca et al. thus explicitly teach that there is no need for debris collection using their device. (*See*, paragraph spanning Cols. 9, 10.) Zacca et al. thus teaches directly against the combination made by the Examiner and the rationale for the combination.

Finally, the Examiner states that the modified Zacca device has the capability of being manipulated to meet the claim limitations because the catheter, torque tube and liner recited in applicants' claims are movable components. This is not true. Applicants' claimed rotatable torque tube is connected, proximally, to the drive system; the proximal end of the catheter terminates within the housing at an aspiration site. And, while the liner is not bonded to the torque tube and the torque tube is freely rotatable within the liner, the liner remains stationary. The language referred to by the Examiner, "a catheter…extending distally to enclose the torque tube and the liner," previously recited in lines 11-12 of claim 19 and section (c) of claim 20, is *not* a recitation of the relative position of two moveable components. Applicants' catheter, torque tube and liner, as claimed, do not and cannot move axially relative to one another. Applicants' claimed structures and structural relationships are expressed in structural language and must be given full patentable weight.

Applicants submit that the pending claims are novel and non-obvious and satisfy the requirements of patentability. Early reconsideration and allowance of the pending claims is respectfully solicited.

Concluding Remarks

If the pending claims are not deemed to be in allowably form as a result of this Amendment and Reply, the undersigned requests a phone interview with the Examiner to discuss applicants' pending claims and their patentability in view of the prior art relied upon for rejection.

Respectfully submitted,

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